April 25, 2025

STERIS Corporation
Logan Persons
Regulatory Affairs Specialist
5960 Heisley Rd
Mentor, Ohio 44060

Re: K243876
Trade/Device Name: VERIFY STEAM Integrating Indicator
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization process indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: December 17, 2024
Received: December 18, 2024

Dear Logan Persons:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2025.04.25 14:59:45 -04'00'

for: Christopher K. Dugard
Director
DHT4C: Division of Infection Control Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243876

Device Name
VERIFY STEAM Integrating Indicator

Indications for Use *(Describe)*
The integrating indicator is designed to chemically react over time with the critical parameters of a steam sterilization cycle within a specified tolerance. The integrating indicator strip is intended to be placed in each pack, pouch, container, tray or other containment device to function as an independent monitor of critical parameters for the following sterilization cycles:

Steam Sterilization Cycles:
- 250°F/121°C, 30 minutes Gravity
- 270°F/132°C, 4 minutes Dynamic Air Removal
- 270°F/132°C, 5 minutes Dynamic Air Removal
- 270°F/132°C, 6 minutes Dynamic Air Removal
- 270°F/132°C, 7 minutes Dynamic Air Removal
- 270°F/132°C, 8 minutes Dynamic Air Removal
- 270°F/132°C, 9 minutes Dynamic Air Removal
- 270°F/132°C, 10 minutes Dynamic Air Removal
- 270°F/132°C, 15 minutes Gravity
- 273°F/134°C, 4 minutes Dynamic Air Removal
- 275°F/135°C, 3 minutes Dynamic Air Removal
- 275°F/135°C, 10 minutes Gravity

Steam Sterilization Cycles (IUSS):
- 270°F/132°C, 4 minutes Dynamic Air Removal
- 270°F/132°C, 3 minutes Gravity
- 270°F/132°C, 10 minutes Gravity
- 275°F/135°C, 3 minutes Dynamic Air Removal
- 275°F/135°C, 3 minutes Gravity
- 275°F/135°C, 10 minutes Gravity

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary (K243876)
For
VERIFY STEAM Integrating Indicator

Sponsor Facility
STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600
Fax: (440) 357-9198

Manufacturing Facility
STERIS Corporation Franklin Park
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Franklin Park, IL 60131
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Contact
Logan Persons
Regulatory Affairs Specialist
Phone: (440) 392-7325
Fax: (440) 357-9198
Email: Logan_Persons@steris.com

Updated Date:
April 24, 2025

STERIS®

1. Device Name

Trade Name:	VERIFY STEAM Integrating Indicator
Common/usual Name:	Chemical Indicator
Device Classification:	Class II
Classification Name:	Indicator, physical/chemical sterilization process [21 CFR 880.2800(b)]
Product Code:	JOJ

2. Predicate Device

Proprietary Name	VERIFY STEAM Integrating Indicator
Common/usual Name	Chemical Indicator
Classification Name:	Indicator, physical/chemical sterilization process [21 CFR 880.2800(b)]
Product Code:	JOJ
510(k) Submitter/Holder	STERIS Corporation
510(k) Number:	K213412

3. Description of Device

The VERIFY STEAM Integrating Indicator is a single use device used by healthcare providers to monitor steam sterilization cycles. The VERIFY STEAM Integrating Indicator is included in a pack, pouch, container, tray or other containment device in a steam sterilizer and the load is processed in accordance with the sterilizer's manufacturer's directions. Prior to the use of the processed items, the integrator is observed. If the dark bar on the device enters the ACCEPT (OK) window, the integrator is read as a PASS to indicate that the steam sterilization criteria for the cycle have been met. If the dark bar on the device does not enter the ACCEPT (OK), the integrator is read as a FAIL, indicating that sufficient steam sterilization criteria has not been met and processed materials should be subjected to another steam sterilization cycle prior to use.

4. Intended Use/Indications for Use

The integrating indicator is designed to chemically react over time with the critical parameters of a steam sterilization cycle within a specified tolerance. The integrating indicator strip is intended to be placed in each pack, pouch, container, tray or other containment device to function as an independent monitor of critical parameters for the following sterilization cycles:

Steam Sterilization Cycles:

- 250°F/121°C, 30 minutes Gravity
- 270°F/132°C, 4 minutes Dynamic Air Removal
- 270°F/132°C, 5 minutes Dynamic Air Removal
- 270°F/132°C, 6 minutes Dynamic Air Removal
- 270°F/132°C, 7 minutes Dynamic Air Removal
- 270°F/132°C, 8 minutes Dynamic Air Removal
- 270°F/132°C, 9 minutes Dynamic Air Removal
- 270°F/132°C, 10 minutes Dynamic Air Removal
- 270°F/132°C, 15 minutes Gravity
- 273°F/134°C, 4 minutes Dynamic Air Removal

- 275°F/135°C, 3 minutes Dynamic Air Removal
- 275°F/135°C, 10 minutes Gravity

Steam Sterilization Cycles (IUSS):

- 270°F/132°C, 4 minutes Dynamic Air Removal
- 270°F/132°C, 3 minutes Gravity
- 270°F/132°C, 10 minutes Gravity
- 275°F/135°C, 3 minutes Dynamic Air Removal
- 275°F/135°C, 3 minutes Gravity
- 275°F/135°C, 10 minutes Gravity

5. **Summary of Technological Characteristics** A comparison of technological characteristics are summarized in **Table 1.**

Table 1. Summary of SCBI Physical Description and Technological Properties

Feature	VERIFY STEAM Integrating Indicator (K243876)	VERIFY STEAM Integrating Indicator (K213412)	Comparison
Intended Use	The integrating indicator is designed to chemically react over time with the critical parameters of a steam sterilization cycle within a specified tolerance. The integrating indicator strip is intended to be placed in each pack, pouch, container, tray or other containment device to function as an independent monitor of critical parameters for the following sterilization cycles: Steam Sterilization Cycles: • 250°F/121°C, 30 minutes Gravity • 270°F/132°C, 4 minutes Dynamic Air Removal • 270°F/132°C, 5 minutes Dynamic Air Removal • 270°F/132°C, 6 minutes Dynamic Air Removal • 270°F/132°C, 7 minutes Dynamic Air Removal • 270°F/132°C, 8 minutes Dynamic Air Removal	The integrating indicator is designed to chemically react over time with the critical parameters of a steam sterilization cycle within a specified tolerance. The integrating indicator strip is intended to be placed in each pack, pouch, container, tray or other containment device to function as an independent monitor of critical parameters for the following sterilization cycles: Steam Sterilization Cycles: • 250°F/121°C, 30 minutes Gravity • 270°F/132°C, 4 minutes Dynamic Air Removal • 270°F/132°C, 5 minutes Dynamic Air Removal • 270°F/132°C, 6 minutes Dynamic Air Removal • 270°F/132°C, 7 minutes Dynamic Air Removal • 270°F/132°C, 8 minutes Dynamic Air Removal	Identical

Feature	VERIFY STEAM Integrating Indicator (K243876)	VERIFY STEAM Integrating Indicator (K213412)	Comparison
	• 270°F/132°C, 9 minutes Dynamic Air Removal • 270°F/132°C, 10 minutes Dynamic Air Removal • 270°F/132°C, 15 minutes Gravity • 273°F/134°C, 4 minutes Dynamic Air Removal • 275°F/135°C, 3 minutes Dynamic Air Removal • 275°F/135°C, 10 minutes Gravity Steam Sterilization Cycles (IUSS): • 270°F/132°C, 4 minutes Dynamic Air Removal • 270°F/132°C, 3 minutes Gravity • 270°F/132°C, 10 minutes Gravity • 275°F/135°C, 3 minutes Dynamic Air Removal • 275°F/135°C, 3 minutes Gravity • 275°F/135°C, 10 minutes Gravity	• 270°F/132°C, 9 minutes Dynamic Air Removal • 270°F/132°C, 10 minutes Dynamic Air Removal • 270°F/132°C, 15 minutes Gravity • 273°F/134°C, 4 minutes Dynamic Air Removal • 275°F/135°C, 3 minutes Dynamic Air Removal • 275°F/135°C, 10 minutes Gravity Steam Sterilization Cycles (IUSS): • 270°F/132°C, 4 minutes Dynamic Air Removal • 270°F/132°C, 3 minutes Gravity • 270°F/132°C, 10 minutes Gravity • 275°F/135°C, 3 minutes Dynamic Air Removal • 275°F/135°C, 3 minutes Gravity • 275°F/135°C, 10 minutes Gravity	
Device Design – components	Backing material with embossed cavity containing temperature sensitive chemical and coloring dye, wicking strip, covered with laminated paper containing labeling and windows.	Backing material with embossed cavity containing temperature sensitive chemical and coloring dye, wicking strip, covered with laminated paper containing labeling and windows.	Similar. Plastic layer was changed
Indicator agent	Proprietary formulation	Proprietary formulation	Identical
Sterilization method and cycles	Steam Sterilization Cycles: • 250°F/121°C, 30 minutes Gravity • 270°F/132°C, 4 minutes Dynamic Air Removal • 270°F/132°C, 5 minutes Dynamic Air Removal	Steam Sterilization Cycles: • 250°F/121°C, 30 minutes Gravity • 270°F/132°C, 4 minutes Dynamic Air Removal • 270°F/132°C, 5 minutes Dynamic Air Removal	Identical

Feature	VERIFY STEAM Integrating Indicator (K243876)	VERIFY STEAM Integrating Indicator (K213412)	Comparison
	• 270°F/132°C, 6 minutes Dynamic Air Removal • 270°F/132°C, 7 minutes Dynamic Air Removal • 270°F/132°C, 8 minutes Dynamic Air Removal • 270°F/132°C, 9 minutes Dynamic Air Removal • 270°F/132°C, 10 minutes Dynamic Air Removal • 270°F/132°C, 15 minutes Gravity • 273°F/134°C, 4 minutes Dynamic Air Removal • 275°F/135°C, 3 minutes Dynamic Air Removal • 275°F/135°C, 10 minutes Gravity Steam Sterilization Cycles (IUSS): • 270°F/132°C, 4 minutes Dynamic Air Removal • 270°F/132°C, 3 minutes Gravity • 270°F/132°C, 10 minutes Gravity • 275°F/135°C, 3 minutes Dynamic Air Removal • 275°F/135°C, 3 minutes Gravity • 275°F/135°C, 10 minutes Gravity	• 270°F/132°C, 6 minutes Dynamic Air Removal • 270°F/132°C, 7 minutes Dynamic Air Removal • 270°F/132°C, 8 minutes Dynamic Air Removal • 270°F/132°C, 9 minutes Dynamic Air Removal • 270°F/132°C, 10 minutes Dynamic Air Removal • 270°F/132°C, 15 minutes Gravity • 273°F/134°C, 4 minutes Dynamic Air Removal • 275°F/135°C, 3 minutes Dynamic Air Removal • 275°F/135°C, 10 minutes Gravity Steam Sterilization Cycles (IUSS): • 270°F/132°C, 4 minutes Dynamic Air Removal • 270°F/132°C, 3 minutes Gravity • 270°F/132°C, 10 minutes Gravity • 275°F/135°C, 3 minutes Dynamic Air Removal • 275°F/135°C, 3 minutes Gravity 275°F/135°C, 10 minutes Gravity	
Mechanism of action	Proprietary	Proprietary	Identical
Endpoint specification	The end point is determined by the migration of the steam sensitive dye to an area marked ACCEPT (OK) on the indicator. Endpoint is reached at the stated value (SV) for each claimed temperature. Endpoint is not	The end point is determined by the migration of the steam sensitive dye to an area marked ACCEPT (OK) on the indicator. Endpoint is reached at the stated value (SV) for each claimed temperature. Endpoint is not	Identical

Feature	VERIFY STEAM Integrating Indicator (K243876)	VERIFY STEAM Integrating Indicator (K213412)	Comparison
	reached at the stated value -15% time and/or -1°C.	reached at the stated value -15% time and/or -1°C.	
Comparison of integrator stated values at biological indicator growth-negative cycle conditions	Integrator does not reach endpoint before the biological indicator is inactivated.	Integrator does not reach endpoint before the biological indicator is inactivated.	Identical
Shelf life	22 Months	5 years	Similar
Standard/ Guidance	Conforms to: • Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Chemical Indicators • ANSI/AAMI/ISO 11140-1:2014: Sterilization of Health Care Products – Chemical Indicators – Part 1: General Requirements	Conforms to: • Guidance for Industry and FDA Staff: Premarket Notification [510(k)] Submissions for Chemical Indicators • ANSI/AAMI/ISO 11140-1:2014: Sterilization of Health Care Products – Chemical Indicators – Part 1: General Requirements	Identical

6. Summary of Non-clinical Tests

Testing was performed to evaluate performance and demonstrate substantial equivalence to the predicate as summarized in Table 2.

Table 2. Performance Testing

Test	Acceptance Criteria	Result
Stated Value Testing per ANSI/AAMI/ISO 11140-1:2014 section 11	• All integrators processed will demonstrate no visible deterioration of the film • All integrators processed in a dry heat cycle will demonstrate a failing result • The Stated Values for time at 121 °C and 135 °C shall be specified and shall not be less than 16.5 min at 121 °C and 1.2 min at 135 °C • The temperature coefficient shall not be less than 10°C and not more than 27°C. • The correlation coefficient shall not be less than 0.9	PASS

Simulated Use Testing	• All integrators processed in a full cycle will demonstrate a passing result with no physical deterioration of the film • All integrators processed in a partial cycle will demonstrate a passing result with no physical deterioration of the film • No integrators will exhibit a leak in the viewing window	PASS
Stability Study	• All CIs processed in pass/full cycles in the BIER vessel will demonstrate pass results and shall not be under minimum specification limits as per the standard ISO 11140-1 • All CIs processed in fail/partial cycles in BIER vessel will demonstrate fail results • All CIs processed for dry heat testing will demonstrate fail results.	PASS
Comparison Testing with Biological Indicator	• The Chemical Indicator does not reach its endpoint before the biological indicator is inactivated.	PASS

7. Conclusion

The VERIFY STEAM Integrating Indicator has met the established performance criteria. Based on the intended use, technological characteristics and non-clinical performance data, the subject device (K243876) is as safe, as effective, and performs as well as the legally marketed predicate device (K213412), Class II (21 CFR 880.2800), product code JOJ.